



PATENT
Attorney Docket No. 402076

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Parikh et al.

Group Art Unit: 1615

Application No. 09/281,430

Examiner: Todd Ware

Filed: March 30, 1999

For: ANTICANCER COMPOSITIONS

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INFORMATION DISCLOSURE STATEMENT

APR 23 2003

Commissioner for Patents
Washington, D.C. 20231

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Pursuant to 37 CFR 1.97 and 1.98, the references listed on the enclosed Form PTO-1449 and/or Substitute Form PTO-1449 ("Form 1449") are submitted for consideration by the Examiner in the examination of the above-identified patent application.

The full consideration of the references in their entirety by the Examiner is respectfully requested and encouraged. Also, it is respectfully requested that the references be entered into the record of the present application and that the Examiner place his or her initials in the appropriate area on the enclosed Form 1449, thereby indicating the Examiner's consideration of each of the references.

The submission of the references listed on the Form 1449 is for the purpose of providing a complete record and is not a concession that the references listed thereon are prior art to the invention claimed in the patent application. The right is expressly reserved to establish an invention date earlier than the above-identified filing date in order to remove any reference submitted herewith as prior art should it be deemed appropriate to do so.

Further, the submission of the references is not to be taken as a concession that any reference represents art that is relevant or analogous to the claimed invention. Accordingly, the right to argue that any reference is not properly within the scope of prior art relevant to an examination of the claims in the above-identified application is also expressly reserved.

The Information Disclosure Statement is being filed:

- ☒ **within** any one of the following time periods: (a) within three months of the filing date of a national application other than a continued prosecution application under 37 CFR 1.53(d); (b) within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 of an international application; (c) before the mailing date of a first Office Action on the merits; or (d) before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

- ☐ **after** (a), (b), (c) or (d) above, but before the mailing date of a final action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and includes *one* of:
- ☐ the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below).
- or*
- ☐ the fee of \$180 set forth in 37 CFR 1.17(p) (see "Fees" below).
- ☐ **after** the mailing date of a final action under 37 CFR 1.113 or a Notice of Allowance under 37 CFR 1.311; or an action that otherwise closes prosecution in the application, and on or before payment of the issue fee, and includes the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below).
- ☐ **after** the mailing date of a Notice of Allowance under 37 CFR 1.311, and on or before payment of the issue fee, and **within** thirty days of receiving each item of information contained in the Information Disclosure Statement, and includes the Statement under 37 CFR 1.704(d) (see "Statement under 37 CFR 1.704(d)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below).
- NOTE: This is for original applications except applications for a design patent, filed on or after May 29, 2000, wherein a paper containing only an Information Disclosure Statement in compliance with 37 CFR 1.97 and 1.98 is being filed.

Copies of the References

-
- ☒ Copies of the references listed on the enclosed Form 1449 are enclosed herewith.
- ☐ A copy of the foreign search report is enclosed herewith.
- ☐ The references listed on the enclosed Form 1449 were previously identified in the parent application(s) of the present application, and copies of the references were furnished at that time. Accordingly, additional copies of the references are not submitted herewith, so as not to burden the file with duplicate copies of references. The Examiner is respectfully requested to carefully review the references in accordance with the requirements set out in the Manual of Patent Examining Procedure. In accordance with 37 CFR 1.98(d), the details of the parent application(s) relied upon for an earlier filing date under 35 USC 120 in which copies of the references were previously furnished are set out below:

U.S. APPLICATIONS		Status (<i>check one</i>)		
U.S. APPLICATIONS	U.S. FILING DATE	PATENTED	PENDING	ABANDONED
1.				
2.				
3.				

Statement under 37 CFR 1.97(e)

- ☐ The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.
- ☐ The **undersigned** hereby states that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

Statement under 37 CFR 1.704(d)

- ☐ The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in 37 CFR 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

Fees

- ☒ No fee is owed by the applicant(s).
- ☐ The **IDS Fee of \$180** under 37 CFR 1.17(p) is enclosed herewith.

Method of Payment of Fees

- ☐ Attached is a check in the amount of \$.
- ☐ Charge Deposit Account No. 12-1216 in the amount of \$. (A duplicate copy of this communication is enclosed for that purpose.)

Authorization to Charge Additional Fees

- ☒ If any additional fees are owed in connection with this communication, please charge Deposit Account No. 12-1216. (A duplicate copy of this communication is enclosed for that purpose.)

In re Appln. of Parikh et al.
Application No. 09/281,430

Instructions as to Overpayment

☒ Credit Account No. 12-1216.
☐ Refund

Respectfully submitted,

Shannon Schemel

Shannon Schemel, Reg. No. 47,926
LEYDIG, VOIT & MAYER
700 Thirteenth Street, N.W., Suite 300
Washington, DC 20005-3960
(202) 737-6770 (telephone)
(202) 737-6776 (facsimile)

Date: April 22, 2003

IDS (Rev. 7/11/2002)

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Substitute for form 1449A/B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known

Sheet	1	of	13	Application Number	09/281,430
				Filing Date	March 30, 1999
				First Named Inventor	INDU PARIKH
				Group Art Unit	1615
				Examiner Name	Todd Ware
				Attorney Docket Number	402076-SKYEPhARMA

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U.S. PATENT DOCUMENTS

Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
		Application or Patent Number	Kind Code			
	A 1	2803582		Cherney	8/20/1957	
	A 2	3137631		Soloway	6/16/1964	
	A 3	3594476		Merrill	7/20/1971	
	A 4	3715432		Merrill	2/6/1973	
	A 5	3755557		Jacobs	8/28/1973	
	A 6	3937668		Zolle	2/10/1976	
	A 7	3960757		Morishita et al.	6/1/1976	
	A 8	4053585		Allison et al.	10/11/1977	
	A 9	4056635		Glen et al.	11/1/1977	
	A 10	4073943		Wretlind et al.	2/14/1978	
	A 11	4078052		Papahadjopoulos	3/7/1978	
	A 12	4089801		Schneider	5/16/1978	
	A 13	4102806		Kondo et al.	7/25/1978	
	A 14	4107288		Oppenheim et al.	8/15/1978	
	A 15	4133874		Miller et al.	1/9/1979	
	A 16	4145410		Sears	3/20/1979	
	A 17	4147767		Yapel, Jr.	4/3/1979	
	A 18	4168308		Wretlind et al.	9/18/1979	
	A 19	4219548		Reller	8/26/1980	
	A 20	4235871		Papahadjopoulos et al.	11/25/1980	
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	A 22	4271196		Schmidt	6/2/1981	
	A 23	4298594		Sears et al.	11/3/1981	
	A 24	4302459		Steck et al.	11/24/1981	
	A 25	4308166		Marchetti et al.	12/29/1981	
	A 26	4309421		Ghyczy et al.	1/5/1982	
	A 27	4316884		Alam et al.	2/23/1982	
	A 28	4320121		Sears	3/16/1982	
	A 29	4328222		Schmidt	5/4/1982	
	A 30	4329332		Couvreux et al.	5/11/1982	
	A 31	4331654		Morris	5/25/1982	
	A 32	4332795		Ghyczy et al.	6/1/1982	
	A 33	4332796		Los	6/1/1982	
	A 34	4340594		Mizushima et al.	7/20/1982	
	A 35	4345588		Widder et al.	8/24/1982	
	A 36	4351831		Growdon et al.	9/28/1982	
	A 37	4356167		Kelly	10/26/1982	

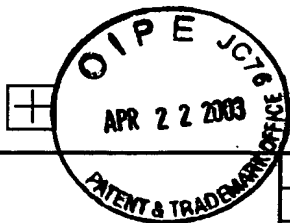
Examiner Signature

Date Considered

* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

+ An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).

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		Application or Patent Number	Kind Code			
	A 3 8	4369182		Ghyczy et al.	1/18/1983	
	A 3 9	4371516		Gregory et al.	2/1/1983	
	A 4 0	4378354		Ghyczy et al.	3/29/1983	
	A 4 1	4394372		Taylor	7/19/1983	
	A 4 2	4397846		Weiner et al.	8/9/1983	
	A 4 3	4411894		Schrank et al.	10/25/1983	
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	A 4 6	4427649		Dingle et al.	1/24/1984	
	A 4 7	4432975		Libby	2/21/1984	
	A 4 8	4448765		Ash et al.	5/15/1984	
	A 4 9	4452817		Imperial Chemical Industrial	6/5/1984	
	A 5 0	4483847		Augart	11/20/1984	
	A 5 1	4485054		Mezei et al.	11/27/1984	
	A 5 2	4492720		Mosier	1/8/1985	
	A 5 3	4515736		Deamer	5/7/1985	
	A 5 4	4522803		Lenk et al.	6/11/1985	
	A 5 5	4610868		Fountain et al.	9/9/1986	
	A 5 6	4613505		Mizushima et al.	9/23/1986	
	A 5 7	4622219		Haynes	11/11/1986	
	A 5 8	4629626		Miyata et al.	12/16/1986	
	A 5 9	4675236		Ohkawara et al.	6/23/1987	
	A 6 0	4687762		Fukushima et al.	8/18/1987	
	A 6 1	4711902		Serno	12/8/1987	
	A 6 2	4719239		Muller et al.	1/12/1988	
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	A 6 5	4758598		Gregory	7/19/1988	
	A 6 6	4762720		Jizomoto	8/9/1988	
	A 6 7	4766046		Abra et al.	8/23/1988	
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	A 6 9	4798846		Imperial Chemical Industrial	1/17/1989	
	A 7 0	4798860		Parr	1/17/1989	
	A 7 1	4800079		Boyer	1/24/1989	

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		Application or Patent Number	Kind Code			
	A 7 2	4801455		List et al.	1/31/1989	
	A 7 3	4803070		Cantrell et al.	2/7/1989	
	A 7 4	4806350		Gerber	2/21/1989	
	A 7 5	4806352		Cantrell	2/21/1989	
	A 7 6	4826687		Nerome et al.	5/2/1989	
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	A 1 0 8	5338761		Nakajima et al.	8/16/1994	
	A 1 0 9	5340564		Illig et al.	8/23/1994	
	A 1 1 0	5346702		Na et al.	9/13/1994	

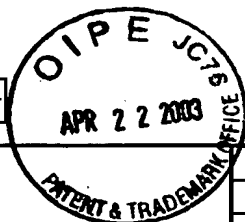
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Examiner Name Todd Ware

Sheet 4 of 13

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U.S. PATENT DOCUMENTS

Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date if Appropriate
		Application or Patent Number	Kind Code			
	A 1 1 1	5352459		Hollister et al.	10/4/1994	
	A 1 1 2	5360593		Bapatia	11/1/1994	
	A 1 1 3	5364633		Hill et al.	11/15/1994	
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	A 1 1 7	5439055		Card et al.	8/8/1995	
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	A 1 3 0	5552160		Liversidge et al.	9/3/1996	
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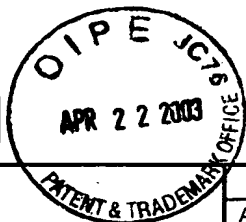
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Sheet 5 of 13

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U.S. PATENT DOCUMENTS

Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
		Application or Patent Number	Kind Code			
	A 1 3 9	5603951		Woo	2/18/1997	
	A 1 4 0	5607694		Marx	3/4/1997	
	A 1 4 1	5618522		Kaleta et al.	4/8/1997	
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	A 1 4 3	5631023		Kearney et al.	5/20/1997	
	A 1 4 4	5637625		Haynes	6/10/1997	
	A 1 4 5	5639474		Woo	6/17/1997	
	A 1 4 6	5648375		Abraham	7/15/1997	
	A 1 4 7	5651982		Marx	7/29/1997	
	A 1 4 8	5651991		Sugiyama et al.	7/29/1997	
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	A 1 5 0	5656289		Cho et al.	8/12/1997	
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	A 1 5 2	5660854		Haynes et al.	8/26/1997	
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	A 1 5 9	5686102		Gross et al.	11/11/1997	
	A 1 6 0	5688528		Carlsson et al.	11/18/1997	
	A 1 6 1	5693337		Suzuki et al.	12/2/1997	
	A 1 6 2	5714520		Jones et al.	2/3/1998	
	A 1 6 3	5719197		Kanios et al.	2/17/1998	
	A 1 6 4	5731355		Jones et al.	3/24/1998	
	A 1 6 5	5731356		Jones et al.	3/24/1998	
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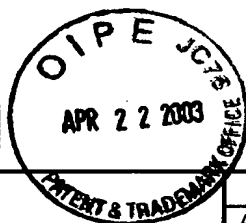
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	A 1 6 7	5750142		Friedman et al.	5/12/1998	
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	A 1 7 0	5776491		Allen, Jr. et al.	7/7/1998	
	A 1 7 1	5776495		Duclos et al.	7/7/1998	
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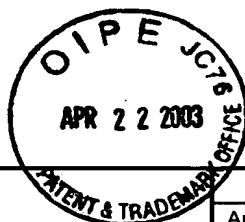
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known

Application Number 09/281,430
Filing Date March 30, 1999
First Named Inventor INDU PARIKH
Group Art Unit 1615
Examiner Name Todd Ware
Attorney Docket Number 402076 SKYEPHARM

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		Application or Patent Number	Kind Code			
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	A 2 0 5	6071928		Curtis et al.	6/6/2000	
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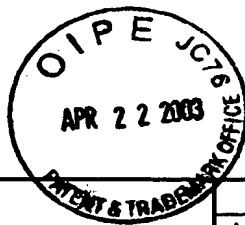
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First Named Inventor	INDU PARIKH
Group Art Unit	1615
Examiner Name	Todd Ware
Attorney Docket Number	402076 SKYEPHARMA

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FOREIGN PATENT DOCUMENTS

Examiner Initials	Doc. No.	Foreign Patent Document			Name of Patentee or Applicant	Date of Publication	Translation	
		Office	Application or Patent Number	Kind Code			Yes	No*+
	A 2 6 1		DE 2 513 797		Imperial Chemical Industries (see reference 4,056,635)	10/9/1975		X ⁺
	A 2 6 2		DE 2 938 807		Green Cross Corp.	11/13/1980		X ⁺
	A 2 6 3		DE 3 421 468		Dr. Rentschler Arzne. (see reference 4,880,634)	12/19/1985		X ⁺
	A 2 6 4		DE 4 440 337		Rainer H. Müller (see reference 5,858,410)	5/15/1996		X ⁺
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	A 2 6 7		EP 0 153 926		Duncan H. Haynes	6/14/1984		
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	A 2 7 6		EP 0 570 829		Dr. Hans Dietl (see reference 5,527,537)	5/12/1993		X ⁺
	A 2 7 7		EP 0 580 690		Sandoz Ltd.	2/2/1994		
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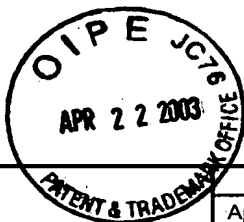
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		Office	Application or Patent Number	Kind Code			Yes	No**
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	A 2 8 6		GB 1 527 638		Laboratories Fournier	3/20/1996		
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Group Art Unit	1615
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Attorney Docket Number	402076 SKYEPHARMA

Sheet 11 of 13

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		Office	Application or Patent Number	Kind Code			Yes	No**
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	A 3 1 5		WO 93/19736		Kabi Pharmacia	10/14/1993		
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	A 3 2 0		WO 96/19064		Xcellenet, Inc.	6/20/1996		
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	A 3 3 0		WO 99/39696		Gensia Sicor Inc.	8/12/1999		
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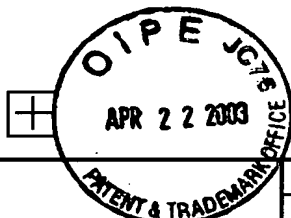
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Sheet	12	of	13	Application Number	09/281,430
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				Group Art Unit	1615
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OTHER - NON PATENT LITERATURE DOCUMENTS

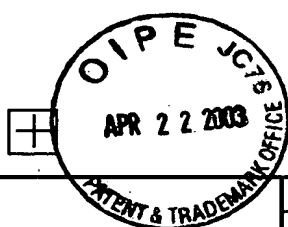
Examiner Initials	Doc. No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Translation	
			Yes	No**
	A 3 3 3	[LSP4]La Fuma Polymery 1998 43 nr 2, 104-108, "The role of water-soluble polymers at the solid/liquid etc."		
	A 3 3 4	"Derived Diameters and Distribution Statistics," from an unknown web-site, 6 pages		
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OTHER - NON PATENT LITERATURE DOCUMENTS

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			Yes	No**
	A 3 5 1	HERBERT A. LEIBERMAN and LEON LACHMAN, Eds., <i>Pharmaceutical Dosage Forms, Tablets</i> , Vol. 1, (1980), p. 13		
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Examiner Signature	Date Considered
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* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

+ An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3)